

REMARKS

The final status of the rejection is premature. The rejections of the claims apply prior art that was not previously applied to reject the claims. Applicants should have an opportunity to respond to the rejections based on this new prior art, without the constraint of a final rejection.

The rejection of claims 1, 3, 4, 10, 11, 15 to 18, 20 and 23 to as being anticipated by Cohen (US 4,991,578) is traversed.

Independent claim 1, on which claims 3, 4 and 10 depend, is directed to a method that: infuses fluid through the catheter into the pericardial sac; constrains the heart with the infused fluid, and reduces dilation of the heart by the constraint on the heart. The other rejected claims have similar limitations.

Cohen discloses infusing small amount of fluid into pericardial sack but does not disclose constraining the heart or reducing dilation of the heart. It would not have been contrary to Cohen to constrain the heart or reduce heart dilation by constraining the heart.

Cohen discloses a method to implant a defibrillation electrode in the pericardial space around a heart. To implant the electrode, Cohen teaches “distending the pericardium from the heart by injecting a small volume of fluid into the pericardium.” Cohen, Abstract. Specifically, Cohen teaches:

A small volume of fluid (e.g., 25-75 cc for humans), such as saline or renografin, is infused into the pericardial space through the fixation catheter and the opening in the atrial wall. This is done for the purpose of distending the pericardial wall away from the heart in order to facilitate a sub-xiphoid entry into the pericardial space. The volume of fluid infused should be less than the amount that would cause cardiac tamponade and dysfunction. [Cohen, col. 7, lns. 22-30 (emphasis supplied)]

Infusing 75 cc will not increase the pressure in the pericardium which normally can receive 120cc of additional fluid without a significant pressure increase. *See* USP 7,226,440 col. 1, Ins. 24-35 (which is owned by the assignee of this application). The pericardial tissue “has a tensile strength similar to that of rubber” and thus is extremely elastic. Watkins et al, *Physicological Role of the Normal Pericardium*, vol. 44, pp. 171-80 at 171 *Annu. Rev. Med.* (1993). Figure 2, shown below, of the Watkins article shows that an injection of over 150 ml (150 cc) is needed to increase the pressure in the pericardial sac in the heart of a dog – which is smaller than that of a human and thus has less fluid than an human heart.

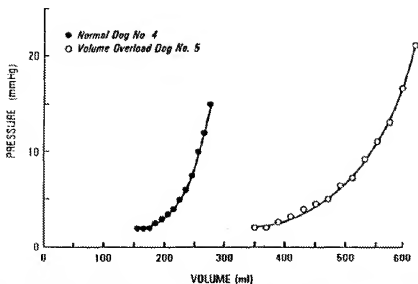


Figure 2 Pressure-volume relation of the pericardium in normal dogs (*solid circles*), and in dogs with chronic cardiac dilation (*open circles*) resulting from abdominal arterio-venous fistula. Reproduced with permission from Freeman & LeWinter (4).

As shown in Figure 2 above, the pressure in the pericardium increases only after about 175 ml of fluid is infused in a dog heart and over 350ml was needed to increase pressure in the heart of a dog suffering from fluid overload. In view of the test results shown in Watkins, the small amounts of fluid, up to 75cc, infused into the pericardium as taught by Cohen will not increase the pressure in the pericardium and, thus, Cohen does not inherently teach increasing a pressure in the pericardium and, particularly, does not teach increasing the pressure in the pericardium sufficiently to constrain the heart.

Cohen teaches infusing just enough fluid to distend the pericardial space such that it separates from the heart but not so much fluid that a cardiac tamponade condition results. This condition occurs which fluid accumulates in the pericardium and compresses the heart such that it cannot expand fully to pump blood. Attached are definitions of cardiac tamponade from Meldine Plus (National Institutes of Health); Wikipedia; and the Free Dictionary. The method recited in claim 1 is directly contrary to Cohen in that the method does increase pressure in the pericardium such that the heart is constrained.

Whereas Cohen teaches to avoid cardiac tamponade, the method recited in claim 1 incurs cardiac tamponade. The method of claim 1 creates a cardiac tamponade condition to compress the heart and reduce the blood volume pumped through a failing heart. By reducing the blood volume pumped by the heart, the method of claim 1 reduces the load and stresses on the heart and thereby relieves a failing heart. Because the method of claim 1 is directly contrary to Cohen which teaches to infuse only a small amount of fluid, the method is patentable over Cohen.

The rejection of claims 1 to 4, 8 to 11, 13, 15 to 38, 36 to 47 as being anticipated by Snyders (USP 6,095,968) is traversed.

Snyders is similar to Cohen with respect to the infusion of a fluid into the pericardial sac. As does Cohen, Snyders discloses a technique to implant defibrillation leads and electrodes by anchoring the leads and electrodes in the pericardium. Snyders, col. 1, lns. 8-13. Snyders at col. 3, lns. 20-23, teaches “injecting a small volume of fluid into the pericardium, thus creating a pericardial effusion. This injection extends the pericardium away from the heart.” The amount of fluid is “25 to 75 cc for humans.” Snyders, col. 7, lns. 22-25. The amount of fluid, the manner of injecting the fluid and the purpose for injecting the fluid disclosed in Snyder is the same as that disclosed in Cohen. Accordingly, Snyders does not anticipate the rejected claims for the same reasons as stated above for Cohen.

The rejection of dependent claims 5 to 9 and 12 as being obvious over Cohen is traversed for the same reasons stated above for the patentability of independent claims 1 and 11.

In addition, claim 8 requires the infusion to continue until the infusion has reached a predetermined pressure level. Cohen does not teach reaching a predetermined pressure level when infusing a fluid. Similarly, claim 9 requires the infusion to increase the pressure in the pericardium to a pressure level of 5 to 10 mmHg. Cohen does not teach reaching the pressure level recited in claim 9 and it would be contrary to Cohen reach such a high pressure level. Cohen teaches infusing a small amount of fluid that will not increase the pressure in the pericardium to any significant effect.

The rejection of dependent claim 14 as being obvious over Snyders is traversed for the same reasons stated above for the patentability of independent claim 11.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

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